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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,651

09/09/2003

Mark A. Reiley

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06/19/2009

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

06/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/658,651	Applicant(s) REILEY, MARK A.	
	Examiner CHRISTOPHER D. PRONE	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/24/09 10/6/08
4/25/08 11/05/07 9/13/07.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a prosthesis system comprising:

A caudal prosthesis that may be fixed at or near a pedicle. The caudal prosthesis includes a joint structure. The system further includes a cephalad prosthesis that may be fixed to the superior vertebral body at or near a pedicle. The cephalad prosthesis includes a joint structure that is to articulate with the caudal prosthesis.

Claim 2, it is not clear how the structure of the device is further defined (as illustrated in elected figure 24) by the function of “adapted and configured to replace a natural articular process”. It appears that the structure as set forth in claim 1 and as illustrated in figure 24 is not further modified by the method steps of claim 2. In fact, it appears that the device as shown in figure 24 is utilized in each method as claimed in claims 1 and claim 2, respectively. (i.e. how does **the structure** of claim 2 differ from the structure of claim 1?).

The same questions of indefiniteness are also applicable with respect to claims 3-26.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Wall [4633722], Homsy, et al [4778472], Morgan [4917701] and Zang [5314486]

The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language, absent structural features, relies solely on a functional use (ie. to replace a certain anatomical feature). It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some portion of the various anatomical structures as set forth in claims 2-26

Each reference illustrates a prosthesis that includes a prosthesis body for fixation to an anatomical bone structure and an artificial joint structure carried by the prosthesis body. In each instance, the devices are capable of performing the function as broadly set forth in the claims.

With respect to claims 27 and 28, each device is made from a medical material from the group of known materials.

Claim 29, the system in each of Wall, Homsy, Morgan and Wall includes a fastening element that is adapted to be installed within a bone.

Claim 30 see screw fasteners in any of Wall, Homsy or Morgan.

Claim 31, see stem of Zang.

Claims 32 and 38, the stem utilizes cement and the screw threads inherently resisting rotation after installation.

Claims 33 and 37, see cement of Zang.

Claim 34, see ingrowth material as taught by Homsy or Wall.

Claims 35 and 36, see screws in any of Homsy, Morgan and Wall.

Response to Arguments

Applicant's arguments filed 10/12/07 have been fully considered but they are not persuasive. The applicant argues that it is clear how claim 2 further limits independent claim 1 from the language. However the language referred to does not recite any actual structure or structural limitations. The language is merely intended use, which the previous examiner referred to as method steps. This intended use is not further limiting because the independent already provides the limitations. The independent recites that the implant replace all of a caudal facet joint which the inherently comprise the articular process of a caudral facet joint required by dependent claim 2. In regards to claims 3-26 the applicant argues that they are not indefinite because each claim requires one or more structural limitations and points out that they are not method claims. However the claims do not recite structural limitations. They are reciting the applicant's intended use

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for the device including its placement and replacement of components. This use language is not defining structural limitations. It is better described as method steps, which the previous examiner referred to them as, which do not overcome the 112 rejection.

Examiner maintains as broadly worded the cited prior art independently show a prosthesis comprising a body including a fastening element that is to be installed within a bony body including an artificial facet joint structure carried by the body spaced from the fastening element where the facet joint is configured to replace all or a portion of the natural joint. By viewing the figures of each reference it is abundantly clear what can be considered the body, the fastening element, and the spaced apart joint.

In response to the applicants arguments directed at the 102/103 rejection, the examiner admits that the recitation of the prosthesis to be used to replace all or a portion of the natural facet joint on a vertebral body is not specifically disclosed in any of the applied references. Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use it reads on the claim. It is the examiner's contention that the devices of the applied references do set forth structure that is capable of performing the intended function, i.e. prosthesis to replace all or a portion of a natural facet joint on a vertebral body. Because the art of record contains all the structure recited within the claims and has an overall general similar structure it is inherent that they could function as required by the claims, which the applicant has

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failed to point out any factual reasoning to the contrary. Applicant is advised to present factual evidence, not opinions to dismiss the art of record from being able to perform as claimed.

The applicant's final argument is that claims 27-38 were not rejected. The examiner disagrees because the body of the rejection included rejection of these claims. The heading for the 102 rejection included a typo, which has been fixed, but it was clear from the body of the rejection that these claims were addresses and rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/Christopher D Prone/

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738